

Notice of Allowability

Application No.

09/897,309

Examiner

Louis K. Huynh

Applicant(s)

ODELL ET AL.

Art Unit

3721

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE filed 04/23/2004 and the Amendment filed 02/25/2004.
2. ☒ The allowed claim(s) is/are 19-29 and 33-40.
3. ☒ The drawings filed on 02 July 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/25/2004 has been entered.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance:

Lawecki (US 5, 687,542) discloses a method of forming prefillable syringe barrel assemblies including the steps of immediately transferring the just formed syringed barrels to an enclosure of class 100 environment in order to maintain a predetermined cleanliness level, and Logothetis (US 4,521,237) discloses a method of forming glass syringe barrels including the step of annealing the glass syringe barrels. However, the method of Logothetis does not concern with maintaining the glass syringe barrels at a predetermined cleanliness; hence, the method requires a further steps of sterilizing the glass syringe barrels. Thus, the prior art of record fails to disclose and/or teach a method of producing prefillable glass syringe barrel assemblies including in combination the steps of annealing the glass syringe barrels at a temperature of at least 500°C, and then immediately transferring the syringe barrels to at least one housing assembly for

Art Unit: 3721

maintaining a predetermined cleanliness level without any sterilization between the annealing and the transferring steps as recited in Claim 19.

Lawecki discloses a method of producing a filled syringe including a step of maintaining the cleanliness of the tip caps by introducing a laminar air flow in order to *prevent* contaminants from settling on the tip caps. However, Applicants in their Remarks in the paragraph bridging pages 10 and 11, filed 02/25/04, have pointed out that air washing is understood in the art as a method of *removing* (e.g. US 5,597,530 to Smith et al.) contaminants from the surface of an article. Thus, the prior art of record also fails to disclose and/or teach a method of producing a filled syringe including in combination the step of air washing the tip caps that are delivered into the environmentally controlled area as recited in Claims 33 and 37.

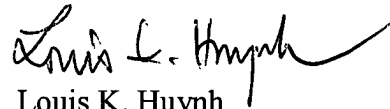
3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is (703) 306-5694. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (703) 308-2187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3721

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Louis K. Huynh
Patent Examiner
Art Unit 3721

June 11, 2004